Commission Regulation (EU) 2016/27 of 13 January 2016 amending Annexes III and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

COMMISSION REGULATION (EU) 2016/27

of 13 January 2016

amending Annexes III and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[(1)], and in particular the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies in animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

(2) According to Article 6(4) of Regulation (EC) No 999/2001 and Chapter B of Annex III to that Regulation, Member States submit to the Commission, each year, information on the monitoring of transmissible spongiform encephalopathies on their territories, and the Commission presents a summary of this information to the Standing Committee on Plants, Animals, Food and Feed.

(3) Following an agreement between the European Commission and the European Food Safety Authority, the preparation and publication of the Union annual summary report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathies will be transferred from the Commission to the European Food Safety Authority. Chapter B of Annex III to Regulation (EC) No 999/2001 should therefore be amended so as to reflect these new modalities.

(4) Annex IV to Regulation (EC) No 999/2001 prohibits the feeding to certain farmed animals of processed animal proteins, in particular those derived from non-ruminants.

(5) In addition, according to point (b)(ii) of Chapter II of Annex IV to Regulation (EC) No 999/2001, fishmeal and compound feed containing fishmeal may be used for feeding non-ruminant farmed animals, including aquaculture animals.

(6) Point 3 of Section A of Chapter III of Annex IV to Regulation (EC) No 999/2001 provides that bulk processed animal protein derived from non-ruminants, and bulk compound feed containing such protein, shall be transported in vehicles and containers which are not used for the transport of feed intended for non-ruminant farmed animals other than aquaculture animals. Since fishmeal and compound feed containing fishmeal are authorised to be used in feed for all non-ruminant farmed animals, this provision should not apply to fishmeal or to compound feed containing fishmeal. Point 3 of Section A of Chapter III of Annex IV to Regulation (EC) No 999/2001 should therefore be amended in order to exclude fishmeal.

(7) Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 provides that the export of processed animal protein derived from non-ruminants, and of products containing such protein, is to be authorised only if they are destined for uses not prohibited by that Regulation and if a written agreement is concluded, prior to the export, between the competent authority of the exporting Member State, or the Commission, and the competent authority of the importing third country, which contains an undertaking from the importing third country to respect the intended use and not to re-export the processed animal protein, or the products containing such protein, for uses prohibited by Regulation (EC) No 999/2001.

(8) This requirement was originally intended to control the spread of Bovine Spongiform Encephalopathy (BSE) at a time when BSE was epidemic in the Union and when the European continent was the main part of the world affected by the epidemic. However, the BSE situation in the Union has since then significantly improved. In 2013, 7 cases of BSE were reported in the Union and in 2014, there were 11 reported cases, compared to 2 166 reported cases in 2001 and 2 124 reported cases in 2002. This improvement of the BSE situation in the Union is reflected in the fact that 20 Union Member States are now recognised as having a negligible BSE risk status in accordance with Commission Decision 2007/453/EC[(2)] as amended.

(9) The requirement laid down in Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 providing the obligation to conclude a written agreement with the third country of destination as a prerequisite for exporting non-ruminant processed animal protein, and products containing such protein, and the prohibition that these products are used in third countries to feed farmed animals, except for aquaculture animals, should therefore be deleted.

(10) Section D of Chapter IV of Annex IV to Regulation (EC) No 999/2001 lays down conditions for the production and use of non-ruminant processed animal-protein destined to be used for feeding aquaculture animals and compound feed containing such protein, which require a complete separation between ruminant and non-ruminant materials at each stage of the production chain, and require regular sampling and analysis to verify the absence of cross-contamination. Those conditions should also be required for non-ruminant processed animal protein, and compound feed containing such protein, intended for export, so as to ensure that exported processed animal protein and compound feed containing such protein provide the same level of safety as those used on the Union territory.

(11) As petfood and fishmeal are produced in processing plants dedicated exclusively to the production of products derived from aquatic animals, except sea mammals, respectively to the production of petfood, the requirement providing that exports are permitted only from establishments, in which the requirements of Section D of Chapter IV of Annex IV to Regulation (EC) No 999/2001 are met, should not apply to petfood or to fishmeal.

(12) Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 should therefore be amended accordingly.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Chapter B of Annex III to Regulation (EC) No 999/2001 is replaced by the following:

CHAPTER B

REPORTING AND RECORDING REQUIREMENTS

I. REQUIREMENTS ON MEMBER STATES

A. **Information to be presented by Member States in their annual report as provided for in Article 6(4)**

1. The number of suspected cases placed under official movement restrictions in accordance with Article 12(1), per animal species.

2. The number of suspected cases subject to laboratory examination in accordance with Article 12(2), per animal species, including the results of the rapid and confirmatory tests (number of positives and negatives) and, with regard to bovine animals, the age distribution of all tested animals. The age distribution should be grouped as follows: “below 24 months”, distribution per 12 months between 24 and 155 months, and “above 155 months” of age.

3. The number of flocks where suspected cases in ovine and caprine animals have been reported and investigated pursuant to Article 12(1) and (2).

4. The number of bovine animals tested within each subpopulation referred to in Chapter A, Part I, points 2.1, 2.2, 3.1 and 5. The method of the sample selection, the results of the rapid and confirmatory tests and the age distribution of the tested animals grouped as set out in point 2 shall be provided.

5. The number of ovine and caprine animals and flocks tested within each subpopulation referred to in Chapter A, Part II, points 2, 3, 5 and 6 together with the method for sample selection and the results of the rapid and confirmatory tests.

6. The geographical distribution, including the country of origin if not the same as the reporting country, of positive cases of BSE and scrapie. The year, and where possible the month of birth shall be given for each TSE case in bovine, ovine and caprine animals. TSE cases which have been considered atypical shall be indicated. For scrapie

cases, the results of the primary and secondary molecular testing, referred to in Annex X, Chapter C, point 3.2(c), shall be reported, where appropriate.

7. In animals other than bovine, ovine and caprine animals, the number of samples and confirmed TSE cases per species.

8. The genotype, and, where possible, the breed, of each ovine animal either found positive to TSE and sampled in accordance with Chapter A, Part II, point 8.1, or sampled in accordance with Chapter A, Part II, point 8.2.

B. **Reporting periods**

The compilation of reports containing the information referred to in Section A and submitted to the Commission (which shall send it to the European Food Safety Authority) on a monthly basis in the electronic format agreed between the Member States, the Commission and the European Food Safety Authority or, with regard to the information referred to in point 8 on a quarterly basis, may constitute the annual report as required by Article 6(4), provided that the information is updated whenever additional information becomes available.

II. INFORMATION TO BE PRESENTED IN THE UNION SUMMARY REPORT

The Union summary shall be presented in a tabled format covering at least the information referred to in Part I.A for each Member State.

From 1 January 2016, the European Food Safety Authority shall analyse the information referred to in Part I and publish by the end of November a summary report on the trends and sources of Transmissible Spongiform Encephalopathies in the Union.

III. RECORDS

1. The competent authority shall keep, for 7 years, records of the information referred to in Part I.A.

2. The investigating laboratory shall keep, for 7 years, all records of testing, in particular laboratory workbooks and, where appropriate, paraffin blocks and photographs of western blots.

Article 2

In Section A of Chapter III of Annex IV to Regulation (EC) No 999/2001, point 3 is replaced by the following:

3. Bulk processed animal protein, other than fishmeal, derived from non-ruminants and bulk compound feed containing such processed animal protein shall be transported in vehicles and containers which are not used for the transport of feed intended for non-ruminant farmed animals other than aquaculture animals.

Article 3

In Chapter V of Annex IV to Regulation (EC) No 999/2001, Section E is replaced by the following:

SECTION E

Export of processed animal protein and products containing such protein

1. The export of processed animal protein derived from ruminants, and of products containing such protein, shall be prohibited.

By way of derogation, that prohibition shall not apply to processed petfood which contains processed animal protein derived from ruminants and which has been processed in approved petfood establishments in accordance with Article 24 of Regulation (EC) No 1069/2009 and is packaged and labelled in accordance with Union legislation.

2. The export of processed animal protein derived from non-ruminants, or compound feed containing such protein, shall be subject to compliance with the following conditions:

(a) the processed animal protein derived from non-ruminants shall originate from processing plants that are dedicated exclusively to processing non-ruminant animal by-products sourced from slaughterhouses and cutting plants referred to in point (a) of Section D of Chapter IV or originate from authorised processing plants which are listed in the publicly available lists referred to in point (d) of Section A of Chapter V;

(b) the compound feed containing processed animal protein derived from non-ruminants shall originate from authorised establishments which are listed in the publicly available lists referred to in point (e) of Section A of Chapter V and shall be packaged and labelled in accordance with Union legislation.

3. The conditions laid down in point 2 shall not apply to:

(a) petfood which contains processed animal protein derived from non-ruminants and which has been processed in approved petfood establishments in accordance with Article 24 of Regulation (EC) No 1069/2009 and is packaged and labelled in accordance with Union legislation;

(b) fishmeal and compound feed containing no other processed animal protein than fishmeal.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 January 2016.

For the Commission

The President

Jean-Claude JUNCKER

(**1**) OJ L 147, 31.5.2001, p. 1.

(**2**) Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84).

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2016/27.